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Stevens Johnson Syndrome Foundation
9285 Utica Street, Westminster, CO 80035
(303) 635-1241

January 26, 2005

Division of Dockets Management (HFA-305),

Food and Drug Administration,

5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852.

REF: Written Testimony from the Stevens Johnson Syndrome Foundation regarding the Joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee

My name is Jean Farrell McCawley. As founder of the Stevens Johnson Syndrome Foundation, a non profit organization, I request that my testimony be entered into the record regarding the joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. As a parent of an infant victim of SJS I am compelled to testify and hopefully save a child in the future from the horror of Stevens Johnson Syndrome.

We have recently seen the media refer to Stevens Johnson Syndrome as a severe skin reaction. Bextra has received a black box warning due to 86 reports of SJS. Vioxx has been taken off the market and Celebrex is under the microscope due to a risk of serious cardiovascular events. What we don't see in NSAIDS used for children is a warning of Stevens Johnson Syndrome and Toxic Epidermal Necrolysis. When these drugs were regulated by prescription, the warning was there. When they went over the counter readily available to the public, the warning was removed. Well-meaning parents are administering these over the counter drugs to their children at the recommendation of their pediatrician. As a result, children are going blind or worse, dying from these over the counter medications. It is the duty of the FDA to change this.

Our children don't get a choice in the medications they are administered. They trust their parents to protect them. We as parents trust their pediatricians to **"First do no harm."** Parents have the right to know that these products can and often harm children.

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The Stevens Johnson Syndrome Foundation has had more reports of SJS to ibuprofen than Bextra, yet Bextra warrants a black box warning. What is wrong with this picture?

We are warned not to administer aspirin to children due to the risk of Reye's Syndrome, yet Stevens Johnson Syndrome, the dirty little secret of the Pharmaceutical companies is referred to it as a "rare skin reaction". Since 1995, the Stevens Johnson Syndrome Foundation has been voluntarily notified of far more cases of this reaction than have been recorded by the FDA. Since the popularity of NSAIDS use in children for rapidly reducing a fever, we have recorded a dramatic rise in reported SJS cases in children.

We have conveyed our reports regarding the reaction in children to Steve Galston, acting director of the FDA. We were told that the FDA has not seen an increase. (See FDA's response dated January 6, 2004).

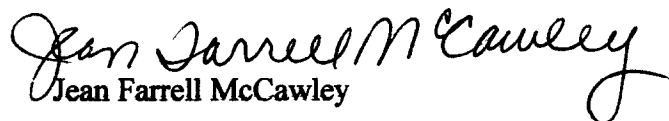
In 2003 we had numerous reports of children with SJS to ibuprofen as well as 2 reports of death. One to over the counter Children's Motrin and one to over the counter Children's Advil.

In 2004 we received 12 reports of children with SJS from over the counter NSAIDS. Within the first two weeks of January 2005 we received reports of 2 children hospitalized with SJS from over the counter NSAIDS. At this rate, the incident of children being permanently disabled or killed outright will easily double last years reported figures. When will the FDA step in and intervene for the safety of our children? How many more will have to die? How many more parents will suffer the guilt of giving this supposedly safe medicine to their children?

The Stevens Johnson Syndrome Foundation strongly advocates that over the counter ibuprofen require a black box warning. We ask that the children not be forgotten and that our testimony be read at this hearing and entered into record.

I have included our brochure for your information. The baby pictured in our brochure is my daughter Julie. As a parent of a child blinded by this reaction as well as the President of this Foundation. I beg you to help us protect the children.

Sincerely,


Jean Farrell McCawley

CC: Kimberly Littleton Topper,
Dornette Spell- LaSane
Senator Ken Salazar
Congresswoman Diana DeGette

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

January 6, 2004

Jean Farrell McCawley
Director
Stevens Johnson Syndrome Foundation
P.O. Box 350333
Westminster, Colorado 80035

Dear Ms. McCawley,

Thank you for your letter of November, 2003, to Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research regarding Stevens Johnson Syndrome (SJS).

In your letter you state that you have seen an increase in reporting of SJS in children from the use of ibuprofen. SJS is a well-recognized, rare adverse event of all nonsteroidal anti-inflammatory drugs (NSAIDs), which includes ibuprofen. The Center for Drug Evaluation and Research's Office of Drug Safety queried our adverse event data base and at this time did not find a trend showing an increase in reporting.

Adverse events are not required to be reported to the FDA and it would not be feasible nor enforceable to mandate reporting by consumers in an over-the-counter setting. However, consumers can play a very important public health role by reporting any adverse reactions (as those you describe in your letter) or other problems with products the agency regulates through our voluntary reporting system, MedWatch. If the FDA receives sufficient reports on one particular drug product, showing that there may be an increasing trend of a particular adverse event associated with that product, we would then take necessary actions. We recommend that you advise those calling your organization to telephone our MedWatch Office at 1-800-FDA-1088 or submit the adverse event/problem electronically via the Internet. A link to the Internet voluntary reporting form can be found by going to the MedWatch homepage at <http://www.fda.gov/medwatch/index.html>, and click on "How to Report".

The FDA considers both the seriousness and the frequency of reported adverse events as well as the estimated number of patients who benefit from the drug. Provided that the public health benefit of the product outweighs its known risks, the FDA allows the continued availability of the drug, but often with revised labeling to better describe the risk and provide warnings to the consumer. It is for this reason that the post marketing MedWatch reports are so important and we encourage consumers to submit the reports on their experience to us.

Thank you for your comments and concerns on this important public health issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Galson", written over a horizontal line.

Steven Galson, M.D., MPH
Acting Director
Center for Drug Evaluation and Research

SJS: WHAT IS IT?

Stevens Johnson Syndrome (SJS), and TENS (Toxic Epidermal Necrolysis)—another form of SJS—are severe adverse reactions to medication. Adverse drug reactions (ADR's) account for approximately 150,000 deaths



per year in the U.S. alone, making drug reactions the fourth leading cause of death in the United States.

SJS is one of the most debilitating ADR's recognized. It was first discovered in 1922 by pediatricians A.M. Stevens and S.C. Johnson after diagnosing a child with severe ocular and oral involvement to a drug reaction.

WHAT CAN CAUSE SJS?

Almost any medication including over-the-counter drugs, such as Ibuprofen, can cause SJS. Most commonly implicated drugs are anti-convulsants, antibiotics (such as sulfa, penicillin and cephalosporin) and anti-inflammatory medications.

WHO CAN GET SJS OR TEN?

Although SJS afflicts people of all ages, a large amount of its victims are children. More female cases have been reported than male, however it does not discriminate against anyone. The SJS Foundation hears from people around the world who suffer from SJS and TEN.



SYMPTOMS, RISKS & TREATMENT

SYMPTOMS

- Persistent fever
- Rash, blisters, or red splotches on skin
- Blisters in mouth, ears, genitalia
- Swelling of eyes
- Conjunctivitis
- Flu-like symptoms

Target lesions are not always seen in SJS!

RISKS

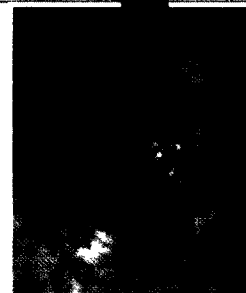
SJS and TEN are life-threatening reactions. If left untreated, they can result in death. Complications can include permanent blindness, dry-eye syndrome, photophobia, lung damage, chronic obstructive pulmonary disease (COPD), asthma, permanent loss of nail beds, scarring of the esophagus and other mucous membranes, arthritis, and chronic fatigue syndrome. Many patient's pores scar shut, causing them to retain heat. These are just some of the side-effects that have been reported.



TREATMENT

First and foremost, affected persons must stop taking the offending drug immediately to prevent complications.

Treatment for SJS is good supportive care. Because patients literally burn from the inside out, burn, infectious disease, ophthalmology and dermatology teams are recommended. IV fluids and high calorie formulas are given to promote healing. Antibiotics are given when necessary to prevent secondary infections such as sepsis. Pain medications such as



morphine are administered to make the patient as comfortable as possible. IVIG treatment can be used in early stages of SJS and TEN.

Most SJS patients can be managed in medical ICU or pediatric ICU. Patients with TEN should be treated in a burn unit.

DRUG REACTIONS: A SERIOUS ISSUE

Drug reactions are one of the leading causes of death in the United States. Yet, less than one percent are reported to the FDA, because there is no mandatory reporting system in effect for post-marketing adverse drug reactions.

Similarly, no one has an accurate count of the cases of SJS and TEN. Although SJS is listed as a rare disease, it may be more prevalent than previously thought.

WHO WE ARE

The SJS Foundation was founded to be a resource to SJS victims and their families. Our mission is to provide support services, and compile and distribute valuable information about SJS to the public and medical professionals regarding treatments and therapies that may prove beneficial to SJS sufferers. We work to promote awareness about the signs of SJS so that a quick diagnosis can be made and the offending agent stopped as soon as possible.

SJS: KNOW THE SIGNS

Recognition of the early symptoms of SJS and prompt medical attention are the most invaluable tools in minimizing the possible long-term effects SJS may have on its victims.



WHAT TO LOOK FOR

- Rash, blisters or red splotches on skin and blistering of the mucous membranes (eyes, ears, mouth, nose, genital area)
- Persistent fever
- Swelling of eyelids, red eyes
- Flu-like symptoms
- Recent history of having taken a prescription or over-the-counter medication

**IF YOU NOTICE TWO OR MORE
OF THESE SYMPTOMS,
CONTACT A PHYSICIAN IMMEDIATELY**

The Stevens Johnson Syndrome Foundation
is a non-profit organization

Your donations are tax deductible and will
provide invaluable aid to a worthwhile cause

To make a contribution to the SJS Foundation,
please contact us at:

Stevens Johnson Syndrome Foundation
9285 N. Ulita St., Westminster, CO 80031

E-mail: sjsupport@aol.com
phone: 303-635-1241

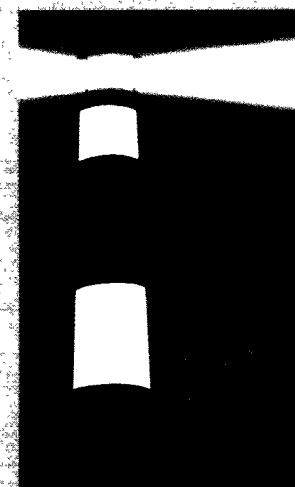
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The facts about

STEVENS JOHNSON SYNDROME (SJS)



**STEVENS
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FOUNDATION**

"Bringing light to the abyss of ignorance"

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